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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,469	02/26/2004	Bret A. Ferree	026,314-005	6985

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EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/787,469	FERREE, BRET A.	
	Examiner	Art Unit	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The replacement drawings received on 18 December 2007 are accepted.

Priority

Applicant's amendment removing the claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The amendment was in response to the notice in the Office action mailed 20 September 2007 that Applicant had not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the prior filed applications do not disclose the use of a graft comprising (bone)-(annulus fibrosis)-(bone), which is found in each of the pending claims 15-25. Thus, the effective filing date filing date of the pending claims in this application is the actual filing date of 26 February 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. (5,681,310; cited by Applicant) in view of Grooms et al. (6,045,554) and Cauthen (6,592,625).

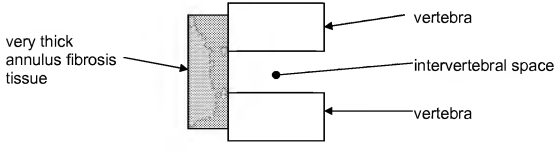
Yuan et al. disclose a spinal repair method, comprising forming a first cavity in a first intervertebral body (Fig. 1, when the top left screw ref. 20 is screwed into place); placing a first segment into the first cavity (Fig. 1, when the top left screw of ref. 20 is screwed into place); forming a second cavity in an adjacent intervertebral body (Fig. 1, when the bottom left screw ref. 20 is screwed into place); placing a second segment into the second cavity (Fig. 1, when the bottom left screw is screwed into place) such that a third segment lies adjacent a defective annulus fibrosis (Fig. 1); securing the device with screws (Fig. 1, when the screws on the right side are screwed into place). Yuan does not disclose forming the first and third segments from allograft or autograft bone or forming the second segment from annulus fibrosis. Grooms et al. disclose a screw made of allograft bone (abstract) which can be utilized with a plate (Fig. 7, ref. 41)(column 6, lines 61-64). This type of bone screw is advantageous since it maintains bone stock and there is no residual hardware (column 7, lines 13-15). In addition, Cauthen discloses a device for the repair of surgical sutures using a patch of human

muscle fascia or any other autograft, allograft or xenograft as a bridge portion. The use of one of these materials act as a platform for fibroblasts or other normal cells of repair (column 4, lines 18-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the first and third segments from allograft bone, in view of Grooms et al., in order to maintain bone stock and eliminate the need for residual hardware. It also would have been obvious to have formed the second segment from allograft annulus fibrosis, in view of Cauthen, in order for the segment to act as a platform for fibroblasts or other normal cells.

With regard to the use of an additional graft (claim 19), it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Likewise, determining the location of the grafts (e.g., resulting in a criss-cross pattern), would have been obvious since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Finally, where the use of graft tissue is already disclosed, it would have been obvious to a person of ordinary skill in the art to substitute or interchange autograft tissue for allograft tissue, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 18 December 2007 is insufficient to overcome the rejection of claims 15-25 based upon as set forth in the last Office action because the conclusions made therein do not necessarily flow from the statements made therein. First, that "it has been reported" that, in order to maximize fusion, the surgeon should maximize surface area support of the intervertebral cage or bone graft, does not prove that every surgeon agrees with this theory, that it is the prevailing theory, or that every surgeon is even aware of this theory. Therefore, this cannot be the foundation for the alleged "teaching away" of using annulus fibrosis tissue as set forth in the rejection. Even if every surgeon did attend the annual meeting at which this position was advanced or did read the article regarding this position and accepted it as fact, Declarant's conclusion does not follow. Declarant maintains that because annulus fibrosis is thick, it necessarily would reduce the size of the bone graft material that can be placed into the disc space. However as illustrated below, that the portion of annulus fibrosis tissue that is used may be thick does not logically lead to a conclusion that it must be at any particular location, and in fact, it need not be within the disc space at all.



Response to Arguments

Applicant's arguments filed 18 December 2007 have been fully considered but they are not persuasive.

The declaration is insufficient to overcome the rejection for the reasons set forth above. Moreover, Applicant would have one believe that Examiner is "ignoring" the teaching in Yuan et al. to use metallic screws and "ignoring" the teaching to use mesh. On the contrary, Yuan et al.--not Examiner--disclose that the screws and the mesh can advantageously be formed of materials other than metal so they can be assimilated by the human body (see col. 2, lines 22-27, reproduced below):

> It must be noted here that the holding mat and the fastening elements of the present invention may be made of a biocompatible material similar to that which is used in making the artificial ligaments, and that the holding mat and the fastening elements of the present invention can be therefore assimilated by the human body.

It is notable that Yuan et al. even goes so far as to mention that the biocompatible materials can be those that are used in making artificial ligaments. Thus, far from teaching away from using anything but metal, as Applicant might have one believe, Yuan et al. recognize that other materials can be quite advantageous. Grooms et al. teaches the use of screws formed of bone and provides motivation to use them. Cauthen teaches not only that muscle fascia can be used, but that *any other autograft, allograft or xenograft* can be used as the bridge portion to act as a platform for normal cells. Thus, not only is Yuan et al. amenable to modification, but also, the teachings and motivation of Grooms et al. and Cauthen are applicable, as set forth in the rejection.

Applicant's arguments regarding, for example, the purported advantages of increased strength between natural bone and annulus fibrosis and of preventing excessive spinal motion are not relevant to the claimed subject matter, since the claims do not recite a minimum strength that is required or a maximum amount of spinal motion that is allowable. Accordingly, the rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo

Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/DC/

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733